**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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**21 CFR Part 558**

## New Animal Drugs for Use in Animal Feeds; Monensin and Tylosin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for use of monensin and tylosin single-ingredient Type A medicated articles to make combination drug Type C medicated feeds used for improved feed efficiency, prevention and control of coccidiosis, and reduction of the incidence of liver abscesses in cattle fed in confinement for slaughter.

**DATES:** This rule is effective [*insert date of publication in the* **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 104–646 that provides for use of RUMENSIN® (20, 30, 45, 60, 80, or 90.7 grams per pound (g/lb) monensin activity as monensin sodium) and TYLAN® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make combination drug Type C medicated feeds for cattle fed in confinement for slaughter. The Type C medicated feeds contain 10 to 30 g/ton monensin and 8 to 10 g/ton tylosin, and are used for improved feed efficiency, prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, and reduction of the incidence of liver abscesses caused by *Fusobacterium*

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*necrophorum* and *Actinomyces (Corynebacterium) pyogenes*. The supplemental NADA is approved as of February 2, 2001, and the regulations are amended in 21 CFR 558.355 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.355 is amended by adding paragraph (f)(3)(xii) to read as follows:

**§ 558.355 Monensin.**

* * * * *

(f) * * *

(3) * * *

(xii) *Amount per ton.* Monensin, 10 to 30 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use.* For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes.*

(*b*) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram monensin per pound of body weight per

day, depending upon the severity of challenge, up to maximum of 360 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day.

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Dated: 2/15/01
February 15, 2001.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Claire M. Lathers

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Director, Office of New Animal Drug Evaluation
Center for Veterinary Medicine.

[FR Doc. 01–???? Filed ??–??–01; 8:45 am]

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